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| KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709 | | | EXAMINER ISABELLA, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,058

Applicant(s)

PAFFORD ET AL.

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 73-116 is/are pending in the application.
- 4a) Of the above claim(s) 110-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,73-82 and 85-109 is/are rejected.
- 7) ☒ Claim(s) 83,84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 110-116 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Accordingly, claims 2,3,73-109 which are readable on the elected species are currently pending for action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3,73-82,85-92,94-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grivas, et al (5514180) in view of Heggeness, et al (5514180) and either of O'Leary et al (5290558) or Prewett et al (5314476)..

Grivas, et al discloses a spinal spacer for insertion into a disc space between adjacent vertebrae including a cylindrical bone dowel having a chamber filled with osteogenic material that serves to promote rapid fusion of the vertebrae. See column 6, lines 38+.

Art Unit: 3738

plugs and the cavity is cleaned. The cavity can then be packed with autogenous bone fragments from the recipient (i.e., when the cavity between adjacent vertebrae is formed, the removed bone fragments can be used as an autogenous packing), hydroxyapatite, BIOGLASS®, mixtures of these elements or any other osteogenic material to promote rapid fusion of the vertebrae between which the dowel is inserted.

While Grivas, et al fails to specifically disclose the use of osteoinductive materials eg. BMP proteins, the use of the proteins to foster and induce new tissue formation to promote fusion between the vertebrae and the spinal spacer is taught by Heggeness, et al. (See column 10, lines 49+). To use BMP as osteogenic material for promoting fusion in the spacer of Grivas, et al would have been obvious to one with ordinary skill in the art from the teachings of Heggeness, et al.

Claims 2,3 see BMP factors as disclosed in column 10, lines 49+.

The present invention is also directed to intervertebral devices comprising at least one osteoinductive material. Suitable osteoinductive materials include, but are not limited to, bone extracts and bone growth factors. Examples of bone growth factors include insulin-like bone growth factors (e.g. IGF-I and IGF-II), transforming growth factor β (e.g. TGF β_1 and TGF β_2), basic fibroblast growth factor (Basic FGF), acidic fibroblast growth factor (acidic FGF), platelet derived growth factor (PDGF), and bone morphogenetic proteins (e.g. BMP-1, BMP-2, BMP-3, BMP-4, BMP-5, BMP-6, and BMP-7). Other terms synonymous with bone growth factors include Somatomedin C, Skeletal Growth Factor, Cartilage Reducing Factor A, Cartilage Reducing Factor B, BMP-2a, BMP-2b, osteogenin, and osteogenic protein-1.

Claim 74, see figure 3A of Grivas, et al.

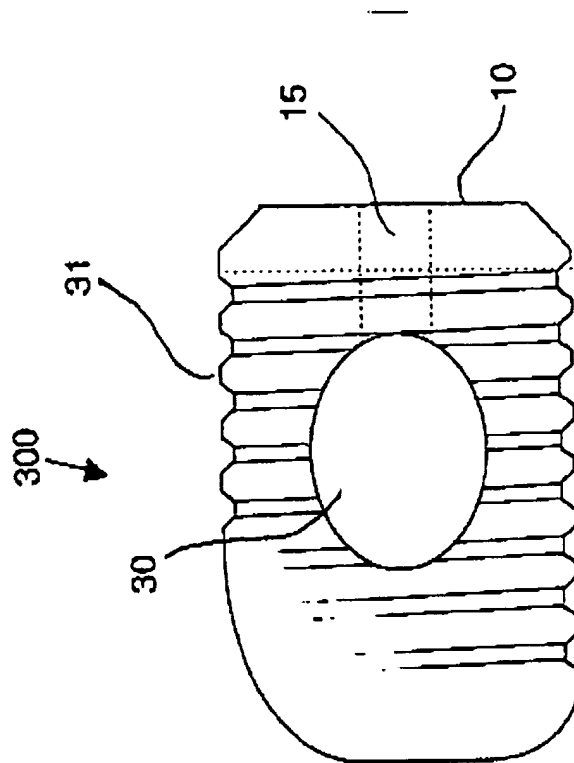


FIG. 3A

Claim 75, the configuration of the implant of Grivas, et al is structurally identical to applicant's implant and therefor would inherently could be used in a method for impacting the dowel into a space between the vertebrae.

Claim 76, the osteogenic material of Heggeness, et al is applied prior to implantation into the vertebral space.

Claims 77-79, see column 10, lines 49+ of Heggeness, et al.

Claims 80 and 81, see Grivas, et al, column 3, lines 5+.

Claim 82, see column 10-11 of Heggeness, et al. Note, the claimed combination of the first and second osteogenic material does not preclude that both materials be

Art Unit: 3738

present in the same matrix and packed in the chamber. With respect to claim 93, see figure 26 of Heggeness, et al.

Claims 85,88 and 89, see tool engaging hole 15 of Grivas, et al (figure 3A). With respect to claim 89, while it is not clear if the tool engaging hole of Grivas, et al is threaded, the use of a threaded hole for engaging an insertion tool is well known in the art as taught, for example only, by Brantigan (5425772) and does not form the novelty of the invention herein.

Claim 86, see thread configuration in Figure 3A of Grivas, et al.

Claims 90-93, the use of water or saline as a carrier for the osteogenic factors is known to be old as taught by each of O'Leary et al and Prewett et al. To use water or saline as a carrier for the proteins of Heggeness, et al as an inexpensive transport medium, would have been obvious to one with ordinary skill in the art from the teachings of O'Leary et al and Prewett et al.

Claim 94 is similar to claim 73 except it does not require the dowel to be cylindrical. Dependent claims 95-106 generally corresponds to the dependent claims 74-93 supra and are similarly rejected accordingly.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grivas, et al (5514180) in view of Heggeness,et al (5514180) and either of O'Leary et al (5290558) or Prewett et al (5314476) and further in view of Brekke (5366508). The use of an osteogenic carrier in the form of a sponge, strip or sheet is clearly taught by

Art Unit: 3738

Brekke. Since Grivas, et al is silent as to the form of the carrier, one with ordinary skill in the art would look to Brekke as a source for exemplary carriers for osteogenic materials.

Claims 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grivas, et al (5514180) in view of Heggeness, et al (5514180) and either of O'Leary et al (5290558) or Prewett et al (5314476) and/or, alternatively, Heggeness, et al in view of Grivas, et al (5814084) and either of O'Leary et al (5290558) or Prewett et al (5314476) and further in view of Bianchi, et al (6033438). The specifics of threads design is taught by Bianchi, et al and if not inherent in Grivas, et al (note the thread design of Grivas, et al '180 as illustrated in figure 3A is identical to the thread design as illustrated in figure 3A of Grivas, et al 6096081) to design the threads of Grivas, et al within the parameters as taught by Bianchi, et al would have been obvious to one with ordinary skill in the art since both references are attempting to solve the same problem, ie. spinal fusion.

Moreover, Applicant's specification, page 5, identifies a source for bone dowels produced and marketed by University of Florida Tissue Bank. The specification goes on to say that the dowels from this source exhibit superior mechanical properties. Please note that the Diaphysial dowel of Grivas, et al comes from the University of Florida Tissue Bank. Page 15, lines 10+, of the specification is the only embodiment disclosed directed to the nature of the threads. The specification lacks any support for criticality to the thread design. Moreover, it appears from the drawings that the threaded dowel of Grivas, et al as shown in figure 3A and the threaded dowel as shown in figure 47 of applicant's specification are identical. In column 7, lines 1+ of Grivas, et al, Grivas, et al

Art Unit: 3738

teaches that the dowels as disclosed have good biomechanical properties that are amenable to machining.

Allowable Subject Matter

Claims 83 and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
2/21/2006